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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,519	08/01/2006	Georg N. Duda	4385-053065	1658

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THE WEBB LAW FIRM, P.C.  
700 KOPPERS BUILDING  
436 SEVENTH AVENUE  
PITTSBURGH, PA 15219

EXAMINER
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DOUGHERTY, SEAN PATRICK

ART UNIT	PAPER NUMBER
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3736

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/553,519	<b>Applicant(s)</b> DUDA ET AL.	
	<b>Examiner</b> SEAN P. DOUGHERTY	<b>Art Unit</b> 3736	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 26-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 26-50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

This is the *final* Office action based on the 10/553519 application filed August 1, 2006. Claims 26-50 are currently pending and have been considered below.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 26, 27, 31-38 and 40-50 are rejected under 35 U.S.C. 102(b) as being anticipated by DiGioia, III et al (US Patent No. 6,205,411: cited in IDS).**

**Regarding claim 26,** DiGioia discloses a method for simulating musculoskeletal strains on a patient for monitoring surgical interventions (col. 7, lines 64-67), the method comprising the steps of (a) determining individual musculoskeletal parameters of the patient (col. 6, lines 49-67), (b) automatically determining the individual musculoskeletal strains from the determined musculoskeletal parameters of the patient (col. 7, lines 11-18), (c) for the automatic determination of the individual musculoskeletal strains, comparing the individual and varied musculoskeletal parameters with musculoskeletal reference parameters filed in a strain database constructed with empirical data (col. 7, lines 19-33; col. 7, lines 48-50), and musculoskeletal reference strains corresponding to the musculoskeletal reference parameters are determined as the individual musculoskeletal strains (col. 7, lines 19-33), the musculoskeletal reference parameters

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being present as discrete values in the strain database (col. 5, line 67 to col. 6, lines 5; col. 6, lines 9-12; col. 7, lines 36-40; col. 7, lines 54-57) and the musculoskeletal reference parameters being compared with the individual musculoskeletal parameters by means of functional relationships (col. 7, lines 46-63) and (d) evaluating the individual musculoskeletal strains in respect of at least one target criterion (col. 7, lines 27-29).

**Regarding claim 27**, DiGioia discloses the method as claimed in claim 26, further comprising the steps of (e) varying at least one of the individual musculoskeletal parameter (col. 7, lines 34-36) to obtain a varied musculoskeletal parameter (col. 7, lines 46-50), (f) subsequently automatically determining the individual musculoskeletal strains taking into consideration the at least one varied musculoskeletal parameter (col. 7, lines 19-33) and (g) subsequently evaluating the individual musculoskeletal strains in respect of the at least one target criterion (col. 7, lines 48-50).

**Regarding claim 31**, DiGioia discloses the method as claimed in claim 27, wherein the variation of the individual musculoskeletal parameters in step e. is carried out taking into consideration predefinable data for implants (col. 7, lines 27-33).

**Regarding claim 32**, DiGioia discloses the method as claimed in claim 26, wherein the individual musculoskeletal strains are calculated from the determined individual musculoskeletal parameters (col. 7, lines 15-18).

**Regarding claim 33**, DiGioia discloses the method as claimed in claim 32, wherein a biomechanical and/or a mathematical model is used as a basis for the calculation of the individual musculoskeletal strains (col. 7, lines 19-22).

**Regarding claim 34**, DiGioia discloses the method as claimed in claim 33, wherein the biomechanical and/or mathematical model is adapted to the individual musculoskeletal parameters (col. 7, lines 22-26).

**Regarding claim 35**, DiGioia discloses the method as claimed in claim 33, wherein the biomechanical and/or mathematical model is chosen on the basis of the determined individual musculoskeletal parameters from at least one database (col. 7, lines 27-45).

**Regarding claim 36**, DiGioia discloses the method as claimed in claim 34, wherein the individual musculoskeletal strains are calculated with the aid of a musculoskeletal model taking into consideration the individual patient anatomy (col. 7, lines 11-18).

**Regarding claim 37**, DiGioia discloses the method as claimed in claim 26, wherein the individual musculoskeletal strains are visualized for evaluation (col. 6, lines 17-21).

**Regarding claim 38**, DiGioia discloses the method as claimed in claim 26, wherein the individual musculoskeletal strains are presented on the basis of an anatomical model, particularly in graph form and/or numerically (col. 6, lines 50-61; col. 7, lines 11-22).

**Regarding claim 40**, DiGioia discloses the method as claimed in claim 26, wherein the individual musculoskeletal parameters of the patient are determined by measurements (col. 6, lines 50-54).

**Regarding claim 41**, DiGioia discloses the method as claimed in claim 40, wherein at least one of the individual musculoskeletal parameters is measured automatically (col. 6, lines 55-58).

**Regarding claim 42**, DiGioia discloses the method as claimed in claim 26, wherein individual movement parameters, particularly gait parameters, are determined (col. 7, lines 19-33), and these are used for the automatic determination of individual musculoskeletal strains (col. 7, lines 46-63).

**Regarding claim 43**, DiGioia discloses the method as claimed in claim 42, wherein the individual gait parameters are determined from personal data stored in a database and/or are recorded individually for one person (col. 7, lines 48-63).

**Regarding claim 44**, DiGioia discloses the method as claimed in claim 26, wherein the position and/or orientation of joints are used for a navigation system for computer-assisted surgery and/or the data from a navigation system are used for computer-assisted surgery (col. 6, lines 24-48).

**Regarding claim 45**, DiGioia discloses a device for evaluating musculoskeletal strains on a patient, with means for carrying out the method as claimed in claim 26 (apparatus, 10).

**Regarding claim 46**, DiGioia discloses a movement analysis system coupled to the device as claimed in claim 45 (col. 6, lines 24-48).

**Regarding claim 47**, DiGioia discloses a navigation system for computer-assisted surgery for carrying out the method as claimed in claim 26 (col. 6, lines 24-48).

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**Regarding claim 48**, DiGioia discloses a method as claimed in claim 26, wherein the musculoskeletal parameters are automatically measured anthropometric parameters (col. 7, lines 1-10).

**Regarding claim 49**, DiGioia discloses a method as claimed in claim 26, wherein the target criterion include contact forces, degree of joint movement, fragment movements of a fracture or any combination thereof (col. 7, lines 46-50).

**Regarding claim 50**, DiGioia discloses a method as claimed in claim 26, further comprising the step of automatically deriving anthropometric parameters from a system for computer-assisted surgery (col. 7, lines 46-63).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

**Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiGioia, III et al (US Patent No. 6,205,411: cited in IDS).**

**Regarding claim 28**, DiGioia discloses the method as claimed in claim 27, wherein a specific target value of at least one target criterion is reached. DiGioia does not appear to explicitly disclose wherein step (e) to (g) are repeated until a specified target value of at least one target criterion is reached. However, it would have been obvious to one of ordinary skill in the art to repeat the steps e. to g. until a specified target value of at least one target criterion is reached as this process is inherent as disclosed by DiGioia. DiGioia establishes the variation of size and orientations of implant components along with the variation of test positions (col. 7, lines 34-36) and simulating various conditions to calculate a range of motion for each condition (col. 7, lines 46-48), comparing each value to a predetermined range of motion to determine an optimized calculated range (col. 7, lines 48-53). It is inherent from the disclosure of DiGioia that steps e. to g. are repeated as this would be done to determine the calculated range from each of the simulations of various conditions to determined the optimized range.

**Regarding claim 29**, DiGioia discloses the method as claimed in claim 28, wherein the individual and varied musculoskeletal parameters corresponding to the target value are output on an output unit, stored in a storage unit and/or transferred to a computer-assisted surgery system and/or to a surgical navigation system (col. 6, lines 24-48).

**Regarding claim 30**, DiGioia discloses the method as claimed in claim 28, wherein the individual and varied musculoskeletal parameters corresponding to the target value serve as a basis for planning a surgical intervention, the positioning of components or the decision regarding the removal of temporary implants (col. 6, lines 24-48).

**Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over DiGioia, III et al (US Patent No. 6,205,411: cited in IDS) in view of Wham et al (US Publication No. 2005/0203504).**

**Regarding claim 39**, DiGioia discloses the method as claimed in claim 26, wherein by evaluation of the individual musculoskeletal strains, a rehabilitation process is evaluated and/or managed (col. 6, lines 21-23). DiGioia does not appear to disclose the method as claimed in claim 26, wherein by evaluation of the individual musculoskeletal strains, a rehabilitation process is evaluated and/or managed, particularly by means of Internet access. However, Wham, a reference in analogous art discloses the method as claimed in claim 26, wherein by evaluation of the individual musculoskeletal strains, a rehabilitation process is evaluated and/or managed, particularly by means of Internet access (§0061).

At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of DiGioia and Wham before him or her to modify the evaluation and/or managing of the rehabilitation process of DiGioia to be evaluated and/or managed by means of Internet access of Wham. The motivation for doing so

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would have been to include instrument operating information, mappings, diagnostic information, algorithms or programs which are updated on a regular basis and downloaded to the generator as needed during surgery (Wham: ¶0061) which can be performed remotely from the surgical theater (DiGioia: col. 6, lines 21-23).

### ***Response to Amendment***

Examiner acknowledges the amendments to claims 26, 27 and 29 and new claim 50 in the amendments filed October 13, 2008.

The claim objections and 112 second paragraph rejections presented in the previous Office action are herein removed by the Examiner.

### ***Response to Arguments***

Applicant's arguments filed October 13, 2008 have been fully considered but they are not persuasive.

Applicant argues that DiGioia fails to disclose a method of simulating musculoskeletal strains because DiGioia fails to mention the term "musculoskeletal strain" or "strain". The Examiner disagrees and respectfully submits that DiGioia discloses musculoskeletal strains even though the cited document does not contain the term "strain".

Examiner notes that the musculoskeletal system is made up of the skeleton, including the bones and respective joints; therefore, the musculoskeletal limitation is fulfilled as DiGioia establishes skeletal structure (40) and joint models (44).

Furthermore, the simulation of range of motion includes "the physiological movement of the leg, described in terms of combined flexion, extension, abduction, adduction and external and internal rotation" (col. 10, lines 57-60), each are terms which involve the movement of bones within joints that produce strains on the respective bones and joints, these movements are considered in "biomechanical simulations of the movement of the joint" (col. 7, lines 20-22). Note that DiGioia establishes such simulations are done to prevent dislocation due to impingement (col. 1, lines 37-50), impingement is also understood as a type of strain on the bones and joints.

Therefore, while not explicitly stated, it is understood that strains play an important role in the determination of range of motion of the musculoskeletal system.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SEAN P. DOUGHERTY whose telephone number is (571)270-5044. The examiner can normally be reached on Monday-Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. P. D./  
Examiner, Art Unit 3736

/Max Hindenburg/  
Supervisory Patent Examiner, Art Unit 3736